

ATTACHMENT - REMARKS

Claims 1, 3, 4, 8 and 10-16 are pending in the present application. By this Amendment, Applicants have amended claims 8 and 11. Applicants respectfully submit that the present application is in condition for allowance based on the discussion which follows.

Claim 11 was rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement for including the phrase “trace elements solution comprises a metal concentration of at least 60 mg/ml,” alleging that the metal concentration limitation comprising “at least 60 mg/ml” introduces new matter into the present claims.

By this Amendment, Applicants have amended claim 11 to now recite that the solution comprises a metal concentration of 60 mg/ml. In reciting that the solution comprises a concentration of 60 mg/ml, Applicants respectfully submit that the claim, using the open ended language “comprising,” means that the trace metal concentration could be greater than 60 mg/ml. It will be readily apparent to one of ordinary skill in the art, based on the present specification, that the injectable concentration, in accordance with the disclosure, can be greater than 60 mg/ml. Furthermore, Applicants respectfully submit that the specification fully enables one to use the disclosed method to produce a trace metal solution having a trace element concentration which is more than 60 mg/ml. Support for this is provided in the method disclosed in Example 6 of the present specification, i.e. the method disclosed can be used to produce a trace element solution having a trace metal concentration which exceeds 60 mg/ml. Accordingly, the metal concentration “comprising 60 mg/ml” represents a threshold metal concentration and,

therefore, the metal concentration could be higher. Moreover, Applicants respectfully submit that the present method fully enables one to produce a trace element solution having a concentration which exceeds 60 mg/ml. In view of the foregoing, Applicants respectfully submit that claim 11 is in full compliance with the requirements of 35 U.S.C. § 112, first paragraph and, therefore, respectfully request that the rejection be withdrawn.

Claims 11, 12, 14 and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,335,116 (hereinafter "Howard"). In the rejection, it was alleged that Howard teaches a stable mineral containing therapeutic composition comprising water soluble complexes of ions of zinc, copper, manganese, chromium and selenium. Referring to Howard, claim 1, the Examiner alleges that the solutions can comprise from 0.1 to 25 mg of zinc, from 0.1 to about 10 mg of copper, from 0.1 to 20 mg of manganese, from 0.01 to 5.0 mg of chromium and from 0.1 to 12.0 mg of selenium (citing Howard, column 5, lines 26-35 and claim 1). The Examiner then alleges that the amount is equivalent to 72 mg/ml.

Contrary to the rejection, Howard fails to provide an enabling disclosure for one of ordinary skill in the art to produce a trace element solution having the alleged 72 mg/ml total metal concentration were one to consider the upper limit of all of the ranges of metal concentrations of claim 1 in Howard. Submitted with this Amendment is a declaration of William Alfred Smith under 37 C.F.R. § 1.132 (hereinafter "Smith Dec."). The specific method used and disclosed in Howard, as well as what would have been known by one of ordinary skill in the art at the time of Howard, would not have allowed one of ordinary skill in the art to produce the presently claimed 60 mg/ml, let alone 72

mg/ml, as alleged by the Examiner (Smith Dec., ¶¶ 4-7 and 10). In fact, all examples in Howard include a substantially smaller concentration than the 60 mg/ml (Smith Dec., ¶¶ 4-8). For example, Howard, column 5, lines 40-45 discloses that the zinc concentration is 0.83 mg/ml, the copper concentration is 0.17 mg/ml, the manganese concentration is 0.67 mg/ml, the chromium concentration is 0.03 mg/ml, the selenium concentration is 0.67 mg/ml and the cobalt concentration is 0.005 mg/ml. Further, Howard, column 5, lines 55-59 disclose a solution having the following ionic concentrations per milliliter: 4.0 mg zinc, 1.0 mg copper, 3.0 mg manganese, 0.50 mg chromium and 5.0 mg selenium. Further, Howard Example 1 discloses a solution per milliliter having 4.0 mg zinc, 1.0 mg copper, 3.0 mg manganese, 0.50 mg chromium and 5.0 mg selenium. Example 2 discloses per milliliter about 0.83 mg zinc, 0.17 mg copper, 0.67 mg manganese, 0.03 mg chromium, 0.67 mg selenium and 0.005 mg cobalt. No other examples are provided.

Moreover, based on the disclosed method in Howard, one of ordinary skill in the art would not have been able to produce a metal concentration of trace elements of 60 mg/ml (Smith Dec., ¶¶ 6, 7 and 10). As an initial point, as far as Applicants are aware, despite the fact that the Howard patent issued in 1982, no product manufactured by this method has been marketed anywhere (Smith Dec., ¶ 7). In contrast, since the priority date of the present application, multiple millions of doses have been sold in the U.S. (Smith Dec., ¶ 7). This is due to the fact that the method of Howard cannot produce a product that can improve the trace mineral status of an animal, particularly due to the low trace mineral concentration caused by the dilution due to the method used by Howard (Smith Dec., ¶¶ 6-8). For example, in Example 1 of Howard, the

solution only achieves a mineral concentration of 13.5 mg/ml, whereas the method according to the present invention produces products with a concentration of upwards of 100 mg/ml and certainly discloses a specific example of 60 mg/ml (Smith Dec., ¶ 6). Applicants respectfully submit that the method according to the present invention is fundamentally new and unique for producing the claimed solution having the claimed concentration which Howard cannot. In fact, the present invention has a trace element concentration which is at least about 4.5 times greater than that of what is disclosed by any actual example of Howard (when comparing the present 60 mg/ml solution to the 13.5 mg/ml [maximum concentration] solution disclosed in Howard) (Smith Dec., ¶ 7).

The reason why the present invention is capable of producing a product with concentrations as disclosed in the present invention is namely due to the use of a continuous process, as compared to Howard's single product approach, and the relative stabilities of the minerals to be supplied (Smith Dec., ¶ 8). In simple terms, 10 ml of a liquid may dissolve 10 mg of a mineral B and simultaneously 10 mg of a mineral C to obtain a 10 ml solution A having 10 mg of B and 10 mg of C (Smith Dec., ¶ 8). However, in accordance with Howard, a separate solution of A is used to dissolve the 10 mg of C, then the two solutions of A are combined to provide a 20 ml solution of A having 10 mg of B and 10 mg of C (Smith Dec., ¶ 8).

Furthermore, Howard uses tetrasodium EDTA, whereas the present invention uses EDTA and/or disodium EDTA (Smith Dec., ¶ 9). The variants used, according to the present invention, have a higher complexing power than tetrasodium EDTA, namely EDTA's acid has a calcium complexing power of 335 mg/g and disodium EDTA has a

calcium complexing power of 266 mg/g, whereas tetrasodium EDTA only has a calcium complexing power of 220 mg/g (Smith Dec., ¶ 9).

Most importantly, the present process as disclosed enables the manufacture of a product comprising higher concentrations than those of Howard, resulting in having the 60 mg/ml trace element solution. This concentration is impossible according to Howard (Smith Dec., ¶¶ 7-10).

Based on the foregoing, Applicants respectfully submit that Howard fails to anticipate the claimed invention. In accordance with *Elan Pharm. Inc. v. Mayo Found.*, 68 USPQ2d 1373 (Fed. Cir. 2003), Howard fails to be anticipatory, since Howard does not teach one of ordinary skill in the art to make or carry out the present invention without undue experimentation. Although Howard discloses various ranges of trace elements, there fails to be any enabling disclosure for one of ordinary skill in the art to produce a trace element solution having concentrations of its trace elements to produce a total trace element concentration of 60 mg/ml, as claimed. Accordingly, Applicants respectfully submit that claims 11, 12, 14 and 16 are not anticipated by Howard.

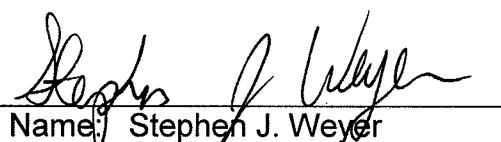
In view of the foregoing, Applicants respectfully submit that the present application is in condition for allowance.

Respectfully submitted,

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